NOV 2 8 2003

510(k) Summary

K031826

Date
November 21, 2003

Submitter
Teknimed, S.A.
11 rue Apollo
31240 L'Union
FRANCE

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Bone void filler

Classification name
Filler, calcium sulfate, preformed pellets (per 21 CFR section 888.3045)

Equivalent Device
TRIHA+ is equivalent in material, indications and use as BIOSORB (K021763) (Sciences et Bio Materiaux, Lourdes, France) and Vitoss™ Scaffold (K994337) (Orthovita, Inc. (Malvern PA).

Device Description
TRIHA+ is an osseo-conductive macroporous implant made of synthetic béta tri calcium phosphate (_-TCP ($Ca_3(PO_4)_2$) indicated for bone void filler. It has a multidirectional interconnected porosity structure, similar to that of the human cancellous bone. The porosity is 60-80% and the size of pores is 200-500µm. TRIHA+ implant slowly resorbs during the remodelling and bone defect repair process and is progressively replaced with bone. The progressive resorption of TRIHA+ is intended to prevent premature resorption.

Intended Use
TRIHA+ is intended for use only as bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. TRIHA+ is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. TRIHA+ should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

TRIHA+ is intended to be gently packed into voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

Summary of Technological Characteristics Compared to Predicate Device
TRIHA+ is similar to the predicate devices in terms of composition, porosity, pore size, and resorption.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Teknimed SA
c/o Mr. J.D. Webb
1001 Oakwood Blvd.
Round Rock, TX 78681
Attn. J.D. Webb

Re: K031826
Trade Name: TRIHA+
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 10, 2003
Received: September 16, 2003

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K03 1826

Device Name: TRIHA+

Indications for Use:

TRIHA+
Indications for Use

TRIHA+ is intended for use only as bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. TRIHA+ is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. TRIHA+ should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

TRIHA+ is intended to be gently packed into voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____(Division Sign-off)
Division of General, Neurological and Restorative Devices

510(k) Number_____

Prescription Use ✓
(per 21 CFR 801.109) OR Over-the-Counter Use ____

(Optional format 1-2-96) _____

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031826